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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,898	03/29/2004	Kazuhiro Ohkouchi	2004_0494	1097

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EXAMINER	
VENKAT, JYOTHSNA A	

ART UNIT	PAPER NUMBER
1615	

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01/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,898	OHKOUCHI ET AL.	
	Examiner	Art Unit	
	JYOTHSNA A. VENKAT Ph. D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,13 and 33-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-13 and 33-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/24/07 has been entered.

Claims 34-39 have been added as per applicant's amendment dated 10/24/07. Claims 12-13 and 33-39 are pending in the application and the status of the application is as follows:

Claim Rejections - 35 USC § 103

Claims 12-13 and 34-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/46215 ('215).

The instant application is claiming a quickly disintegrating solid preparation comprising:

a. An active ingredient

b. Sugar alcohol or saccharide with a mean particle diameter of 30-300 microns

c. Disintegrating agent (carmellose calcium, carboxymethylstarch sodium, croscarmellose sodium or crosspovidone)

d. Cellulose compound (crystalline cellulose, powder cellulose, low substituted hydroxy propyl cellulose or carmellose)

WO '215 teaches all the claimed ingredients in rapidly dissolving dosage form. See the abstract, see pages 4-5, see pages 7-9 for the active ingredients, and see page 17, lines 13-26 for claimed b. The mean particle taught by the document is within the claimed range. See paragraph

bridging pages 17-18 for the various saccharide or sugar alcohols. See page 25 for wicking agent. Some of the agents are the species claimed under c as well as d. See the same page, lines 13-20 for povidone of claimed d. See examples where WO document teaches using both c and d in the compositions.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare rapidly dosage forms using all the ingredients of WO document. One of ordinary skill in the art would have reasonable expectation of success that the claimed dosage form with ingredients would also dissolve rapidly, since using ingredient c helps in transport moisture into the dosage form, and the use of ingredient b helps in the production of a hard, non-friable, directly compressible and rapidly dissolvable in-mouth dosage form. Absent a showing the criticality of the claimed range of the sugar alcohols, the claims are rendered prima facie obvious over WO document.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/46215 ('215) as applied to claims 12-13 above, and further in view of U. S. Patent 6,923,988 ('988).

WO as applied above. The difference is WO document does not teach the claimed active ingredients. However patent '988 teaches solid carriers for improved delivery of active ingredients in pharmaceutical compositions. See the abstract, see col.s 4-8 for the active ingredients, see claim 29 for the claimed pioglitazone. Accordingly, it would have been obvious to one of ordinary skill in the art to use the claimed pioglitazone of patent into the compositions of WO document. One of ordinary skill in the art would be motivated to use the specific active ingredient with the reasonable expectation of success that the compositions with the specific

active ingredient would dissolve rapidly and also increase the bioavailability of the active ingredient. This is a prima facie case of obviousness.

Response to Amendment

The declaration under 37 CFR 1.132 filed 9/19/06 is insufficient to overcome the rejection of claims 12-13 based upon WO 98/46215 ('215) as set forth in the last Office action because:

1. Examples 2-4 recite only particle size of 45 microns (see page 2 of the declaration)
2. Examples 2-4 do not recite particle size of 130 microns. This is also true for example 8. There is no particle diameter of 130 microns in example 8 (see page 2 of the declaration)
3. Examples 5-7 do not recite particle size of 130 microns (see page 2 of the declaration)
4. Examples 10-12 and 14-15 recite larger particle size and the particle size mentioned at page 2 of the declaration correspond to sugar alcohols that are pulverized. *None of the claims recite that the sugar alcohols are pulverized.*
5. All the examples are specific to active ingredient. Claims 12-13 do not recite active ingredient.
6. Therfore the results are not commensurate with the scope of particle diameter of the sugar alcohols.

Note that there is overlap with the particle diameter claimed and the particle diameter disclosed in the WO document with respect to sugar alcohols. Therefore WO document is

also expected to give the solid preparations meeting the criteria of fluidity during tabletting, binding property, adhesion to punch, hardness and intra oral disintegration time.

In view of the above reasons, the declaration is ineffective.

Applicanst arguments (dated 10/24/07) with respect to examiners reasons for declaration being ineffective are same as arguments dated 6/19/07.

Response to Arguments

Applicant's arguments filed 10/24/07 have been fully considered but they are not persuasive.

See below for the data in the declaration, which was submitted on 9/19/06.

5. In order to show that an intraorally quickly disintergating solid preparation having excellent properties can be obtain by using a saccharide or sugar alcohol with a mean particle diameter of 30 μm to 300 μm without any problem in productivity, the mean particle diameter in Examples and Comparative Examples disclosed in the above-identified application are summarized below.

Example and Comp. Ex. Nos.	Saccharide/ sugar alcohol	Mean particle diameter (μm)
Example 1	D-mannitol	130
Example 2	D-mannitol	45 and 130
Example 3	D-mannitol	45 and 130
Example 4	D-mannitol	45 and 130
Example 5	D-mannitol	130
Example 6	D-mannitol	130
Example 7	D-mannitol	130
Example 8	lactose/D-mannitol	80 and 130
Example 9	trehalose	44
Example 10	trehalose	185
Example 11	erythritol	178
Example 12	xylitol	135
Example 13	maltitol	181
Example 14	erythritol	75
Example 15	sorbitol	43
Comp. Example 1	D-mannitol	21
Comp. Example 2	D-mannitol	21

In response to items 1-3 of final rejection, applicants point out that examples 1-3 and 5-7 use 130 microns for mannitol.

The examiner agrees, however this particles size is for mannitol only and not for lactose. WO document teaches lactose as well as mannitol claimed. The particle size is 10-80 microns. There is overlap of particle size from 30-80 microns. Declaration has no data with respect to lower end point for mannitol, which is 30 microns. There is no data for lactose. See below for page 17, which teaches claimed particle size and paragraph bridging pages 17-18 for sugars and sugar alcohols. This includes claimed mannitol and lactose.

> **Generally, direct compression excipients, particularly fillers and binders, are specialty excipients. In most cases, they are common materials that have been physically modified to impart greater fluidity and compressibility. In the case of sugars, such as, for example, dextrose, this generally means granulation to increase particle size. Direct compression mannitol, for example, generally has a minimum of at least about 80% average particle size over 100 microns. Other commercially available direct compression mannitols have a minimum particle size standard of greater than 90% over 200 microns. The opposite is true of the fillers in accordance with the present invention. While direct compression fillers may have at least 85% of the particles over 100 microns in size, often 85% of the particles of filler used in the present invention are significantly under 100 microns. In accordance with the present invention, average particle size generally ranges from between about 10 and about 80 microns, and most preferably, between about 20 to about 65 microns.**
>
> **Particularly preferred fillers, in accordance with the present invention are non-direct compression sugars and sugar alcohols which meet the specifications discussed above. Such sugars and sugar alcohols include,**

without limitation, dextrose, mannitol, sorbitol, lactose and sucrose. Of course, dextrose, for example, can exist as either a direct compression sugar, *i.e.*, a sugar which has been modified to increase its compressibility, or a non-direct compression sugar.

Comparative example uses only mannitol and the particle size tested for comparative example is 21 microns and this is less than the claimed 30 microns. There is no data for mannitol with claimed particle size of 30 microns (emphasis added).

Note that there is overlap with the particle diameter claimed and the particle diameter disclosed in the WO document with respect to mannitol and lactose having particle size of 30-80 microns. Therefore WO document is also expected to give the solid preparations meeting the criteria of fluidity during tabletting, binding property, adhesion to punch, hardness and intra oral disintegration time.

The showing is not commensurate with the particle size for mannitol and lactose.

The declaration is ineffective, therefore rejection of claim 33 under 35 U.S.C. 103(a) as being unpatentable over WO 98/46215 ('215) as applied to claims 12-13 and 34-39 above, and further in view of U. S. Patent 6,923,988 ('988) is also maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JYOTHSNA A. VENKAT/ Ph. D
Primary Examiner
Art Unit 1615

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